

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA <i>ex rel.</i>	§	
James Banigan and Richard	§	
Templin, STATE OF CALIFORNIA,	§	
<i>et al.</i> ,	§	
	§	
Plaintiff,	§	
	§	
VS.	§	CIVIL ACTION H-08-3314
	§	
ORGANON USA, INC.,; ORGANON	§	
BIOSCIENCES, N.V.; SCHERING	§	
PLOUGH CORPORATION; AKZO NOBEL	§	
N.V.; ORGANON INTERNATIONAL,	§	
INC.; ORGANON PHARMACEUTICALS	§	
USA, INC.; and MERCK CO. & INC.,	§	
	§	
Defendants.	§	

OPINION AND ORDER

Pending before the Court in above referenced *qui tam*
action are two motions filed by the Organon Defendants¹: (1)

¹The term "Organon Defendants" or "Organon" refers collectively to Akzo Nobel, N.V., Organon USA, Inc., Organon Pharmaceuticals USA, Inc. Organon International, Inc., and Organon Biosciences N.V. The First Amended Complaint asserts that the Organon Defendants are related entities sharing common employees, offices and business names and are jointly and severally liable under theories of *respondeat superior* and vicarious liability and should be deemed a single entity. Defendants Organon USA, Inc. and Organon Biosciences, N.V. are collectively referred to as "Organon IBS."

Furthermore Relators James Banigan and Richard Templin maintain that successor liability applies here. Schering-Plough purchased, and is the successor-in-interest to, the IBS Defendants and has assumed their rights, duties and liabilities, including with respect to this lawsuit. #81 at 15. On November 3, 2009 Schering Plough Corporation merged with and changed its name to Merck Co. & Inc. ("Merck"), which is thus in turn the successor-in-interest to Schering-Plough and the Organon IBS Defendants and has assumed their rights, duties and liabilities.

motion to for reconsideration (instrument #106) under Federal Rules of Civil Procedure 59(e) and 54(b) of the Court's Opinion and Order (#102) denying Defendants' motion to dismiss (#82); and, if the Court denies the motion for reconsideration, (2) motion to certify issues for interlocutory appeal (#111).

Motion to Reconsider (#106)

In response to the motion to reconsider, Plaintiff-Relators James Banigan and Richard Templin attach as Exhibit A a copy of the United States' Notice of Additional Case Law ("Notice"), filed on February 14, 2013 in *United States of America ex rel. Lauren Kieff and William LaCorte, et al. v. Wyeth*, Case No. 1:06-cv-11724, in the United States District Court, District of Massachusetts. It discusses at length this Court's Opinion and Order of February 1, 2013, a copy of which was attached to the Notice when filed.

This Court has reviewed its Opinion and Order (#102) and finds no reason to modify it. Thus it denies the motion to reconsider.

Motion to Certify for Interlocutory Appeal (#111)

Accordingly, the Court examines Defendants' motion to certify two issues for interlocutory appeal under 28 U.S.C. § 1292(b)²:

Id.; #82, p. 8, n.1.

² Section 1292(b) provides,

When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that

(1) whether an objective reasonableness standard should apply in evaluating whether Organon's interpretation of the nominal price provisions of the Medicaid Rebate Act, 42 U.S.C. § 1396r-8, and the Medicaid Rebate Agreement could support a reverse false claim; and

(2) whether the nominal provision of the Medicaid Rebate Act, 42 U.S.C. § 1396r-8, and the Medicaid Rebate Agreement require "that where a pharmaceutical manufacturer's nominal price is contingent upon other purchase arrangements, all must be considered in calculating the best price, and only afterwards in a separate step should the court determine whether the 'merely nominal' exception applies." Order at 102-03.

Organon Defendants argue that these issues are ripe for immediate appellate review under 28 U.S.C. § 1292(b) "for several reasons. First, they raise purely legal issues that are controlling because if resolved in Organon's favor, Relators' nominal price claims would be dismissed in their entirety. Second,

an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order. The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order, if application is made to it within ten days after entry of the order: *Provided, however,* That application for an appeal hereunder shall not stay proceedings in the district court unless the district judge or the Court of Appeals of a judge thereof shall so order.

they arise in unsettled areas of law about which there is substantial ground for difference of opinion. Finally an appellate decision would materially advance this litigation by avoiding expenditure of unnecessary time and resources, including discovery and trial on significant and complex claims against Organon. Organon Defendants urge that courts have frequently found interlocutory review to be appropriate in cases requiring novel interpretations of the False Claims Act, including complex healthcare reimbursement and rebate. *See, e.g., United States v. Caremark, Inc.*, 634 F.3d 808 (5th Cir. 2011); *United States v. Baylor Univ. Med. Ctr.*, 469 F.3d 263 (2d Cir. 2006); *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005). Thus they ask the Court to certify the two issues for interlocutory appeal and to stay discovery and trial proceedings regarding Relators' best price claims until the Fifth Circuit resolves these issues.

In response, Relators object that there is no substantial ground for disagreement despite Defendants' objections to the Court's rulings. Disagreement with a court's ruling does not constitute a substantial difference,³ nor does disagreement with

³ *See also, e.g., U.S. ex rel. Branch Consultants, LLC v. Allstate Ins. Co.*, 668 F. Supp. 2d 780, 813-14 (E.D. La. 2009) ("substantial ground for difference of opinion" is not the same as disagreement with a district court's ruling).

applicable precedent.⁴ *Ryan v. Flowserve Corp.*, 444 F. Supp. 2d 718, 724 (N.D. Tex. 2006), citing *Wausau Business Ins. Co. v. Turner Const. Co.*, 151 F. Supp. 2d 488, 491 (S.D.N.Y. 2001)(Under 28 U.S.C. § 1292, "'only exceptional circumstances [will] justify a departure from the basic policy of postponing appellate review until entry of a final judgment.'"). See also *United States v. Garner*, 749 F. 281, 286 (5th Cir. 1978)(interlocutory appeals under 28 U.S.C. § 1292(b) are an exception to the general policy against piecemeal appellate review and should only be granted in "exceptional cases"); *Coopers & Lybrand v. Livesay*, 437 U.S. 463, 475 (1978)(only "exceptional circumstances" justify a departure from the basic policy of postponing appellate review until after the entry of a final judgment).

Furthermore the statute allows for interlocutory appeal of an order from the district court, not simply of a controlling question identified by the court or the defendant. 28 U.S.C. § 1292(b); *Yamaha Motor Corp. USA v. Calhoun*, 516 U.S. 199, 205 (1996); *Linton v. Shell Oil Co.*, 563 F.3d 556, 557 (5th Cir. 2009). If certified, the appellate court may opine on any issue included in the order. *Yamaha*, 516 U.S. at 205.

⁴See, e.g., *In re Flor*, 79 F.3d 281, 284 (2d Cir. 1996)("the mere presence of a disputed issue that is a question of first impression, standing alone, is insufficient to demonstrate a substantial difference of opinion"); *White v. Nix*, 43 F.3d 374, 378 (8th Cir. 1994)("substantial ground for difference of opinion does not exist merely because there is a dearth of cases").

The majority of courts have held that it is inappropriate to decide a *scienter* issue, e.g. whether Organon had a "good faith interpretation of the statute" that would negate the intent necessary for an FCA violation, at the pleading stage of the litigation. *U.S. ex rel. Wilkins v. N. Am. Constr. Corp.*, 173 F. supp. 2d 601, 639 (S.D. Tex. 2001), *overruled on other grounds*, 575 F.3d 458, 469 (5th Cir. 2009); *U.S. v. Honeywell Int'l Inc.*, 798 F. Supp. 2d 12, 22-23 (D.D.C.2011)(*scienter* may be examined on summary judgment, but not on a motion to dismiss). Regardless, that would be a factual question, not a question of law and not proper for an interlocutory appeal. Moreover Relators further insist that Defendants' conclusory assertions that this Court has misinterpreted the meaning of "nominal" in the Medicaid Rebate Act and the Medicaid Rebate Agreement and that it is an issue of first impression in the Fifth Circuit do not constitute substantial ground for disagreement. A number of courts have addressed the issue of the reasonableness of a defendant's interpretation of ambiguous provisions in statutes, regulations or contracts on a full factual record at the summary judgment state. *See, e.g., U.S. ex rel. Farmer v. City of Houston*, 523 F.3d 333, 340 (5th Cir. 2008)(*scienter* addressed only after a full factual record is developed).

Moreover, certifying the two issues for appeal would not materially advance this case because Relators' claims regarding

best price would remain pending and because the damages relating to the issues for certification overlap with those of the best price claims.⁵ Also remaining would be Relators' claims about Tice BCG from 1999-2005 regarding Organon's alleged kickbacks to physicians in exchange for prescribing its cancer drug. "The Fifth Circuit has held that certification is particularly inappropriate when a party has claims remaining for adjudication by the finder of fact." *Coates v. Brazoria County, Texas*, No. 10-CV-00071, 2013 WL 321616, *3 (S.D. Tex. Jan. 28, 2012), citing *U.S. v. Bear Marine Servs.*, 696 F.2d 117, 120 (5th Cir. 1983), *abrogated on other grounds*, *U.S. v. Lee*, No. 81-3251, 368 Fed. Appx. (5th Cir. Mar. 4, 2010), and *Spurlin v. Gen. Motors Corp.*, 426 F.2d 294, 294-95 (5th Cir. 1970). An interlocutory appeal would fragment this case and increase delay. Relators suggest that delay is Defendants' motivation for the motion to certify.

If the Court grants the motion to certify, Relators oppose a stay of discovery on their best price claims. The Movant bears a heavy burden to demonstrate why a stay should be granted absent statutory authorization. *Coastal (Bermuda) Ltd. v. E.W. Saybolt & Co.*, 761 F.2d 198, 204 n.6 (5th Cir. 1985) ("Generally, the moving party bears a heavy burden to show why a stay should be granted

⁵ Interlocutory appeal is not appropriate and will not appreciably save time when claims and discovery overlap factually with remaining claims. *Isra Fruit Ltd. v. Agrexco Agr. Export Co.*, 804 F.2d 24, 25-26 (2d Cir. 1986).

absent statutory authorization, and a court should tailor its stay so as not to prejudice other litigants undulyWhere a discretionary stay is proposed, something close to genuine necessity should be the mother of its invocation."). Organon Defendants have failed to show that their motion is supported by "genuine necessity."

In their Reply (#117), Organon Defendants reiterate their argument that because there is a circuit split on the issue of whether an objectively reasonable interpretation of a potentially ambiguous contract provision is a proper basis for dismissal of a False Claims Act case at the pleading stage, it reinforces the need for interlocutory review. #117 at p.2.

Court's Decision

After reviewing the record and the applicable law, the Court finds that Relators as a matter of law have the better part of argument and that an interlocutory appeal on the two issues should not be certified. Interlocutory appeals are "exceptional" and "assuredly do not lie simply to determine the correctness of a ruling." *Clark-Dietz & Assocs.-Engineers, Inc. v. Basic Construction Co.*, 702 F.2d 67, 67-69 (5th Cir. 1983). The statute gives the district court discretion to certify an order that involves a controlling question of law regarding which there is a substantial difference of opinion and where it finds that an immediate appeal may materially advance the ultimate termination of

the litigation, the governing standards. *U.S. v. Caremark, Inc.*, 634 F.3d 808, 814 (5th Cir. 2011), as does the appellate court whether to entertain the appeal.

The Fifth Circuit clearly follows the rule that "[u]nder § 1292(b) it is the order, not the question that is appealable." *Castellano-Contreras v. Decatur Hotels, LLC*, 622 F.3d 393, 398 (5th Cir. 2010), citing *Yamaha Motor Corp.*, 516 U.S. at 205. Organon Defendants have violated this rule. Moreover the Court's review is limited to controlling questions of law. *U.S. v. Caremark, Inc.*, 634 F.3d at 814. As Relators point out, whether Organon had a "good faith interpretation of the statute" involves factual determinations. Organon Defendants have not shown that a reversal of this Court's ruling would terminate the litigation. "'Every ground in § 1292(b) must be met in order for the interlocutory appeal to be considered; these are not factors to be weighed and balanced.'" *Mosaic Underwriting Serv. Inc. v. Moncia Marine Operations, LLC*, 2013 WL 2903083, *10 (E.D. La. June 12, 2013), quoting *Panda Energy Int'l, Inc. v. Factory Mut. Ins.*, No. 11-003, 2011 WL 610016, *4 (N.D. Tex. Feb. 14. 2011), citing *Ahrenholz v. Bd. of Tr. of Univ. of Ill.*, 219 F3d 674, 676 (7th Cir. 2000)("Unless all these criteria are satisfied, the district court may not and should not certify its order to us for an immediate appeal under section 1292(b)."). See also *Adhikari v. Daoud & Partners*, Civ. A. No. 09-cv-1237, 2010 WL 744237, *3 (S.D. Tex.

March 1, 2010)(same).

The Court finds that Organon Defendants have not met their burden of proof to show "substantial ground for difference of opinion" or that an immediate interlocutory appeal might materially advance the ultimate termination of the litigation, while Relators have shown that these governing standards have not been met here. Therefore it denies the motion to certify.

Accordingly, for the reasons stated above, the Court
ORDERS that Organon Defendants' motion for reconsideration (#106) and motion to certify for interlocutory appeal (#111) are DENIED.

SIGNED at Houston, Texas, this 6th day of September, 2013.



MELINDA HARMON
UNITED STATES DISTRICT JUDGE